REMARKS

STATUS OF THE CLAIMS:

Claims 1 to 52, 60, and 67 to 75 are cancelled.

Claims 53 and 76 were amended.

New Claim 77 was added.

Claims 53 to 59, 61 to 66, and 76 to 77 are pending.

Claim 53 has been amended to delete sub-clause "(d)" in its entirety, and to delete the term "; and" to place this claim in proper Markush format in consideration of the deletion of sub-clause "(d)" to place this claim in better condition for allowance. Applicants assert that these amendments were not made to overcome any issues related to the patentability of this claim and that Applicants right to equivalents of Claim 53 is reserved. No new matter has been added.

Claim 76 has been amended to delete the phrase "and (d)" in its entirety, and to append the term " and" after the "(c)" term in order to reflect deletion of sub-clause "(d)" in Claim 53, and to place this claim in proper Markush format in consideration of the same. Applicants assert that these amendments were not made to overcome any issues related to the patentability of this claim and that Applicants right to equivalents of Claim 76 is reserved. No new matter has been added.

Support for new Claim 77 may be found in original Claim 53. No new matter has been added.

I. Rejections under 35 U.S.C. § 101

a. The Examiner has rejected Claims 53 to 66 and 76 under 35 U.S.C. § 101, for failure to demonstrate a credible, substantial, specific, or a well-established utility. More particularly, the Examiner alleges that "Applicant asserts that the associations of expression of a claimed polynucleotide with testicular cancer, a "neoplasm", among neoplasms of six other endocrine organs, and among twenty other organs, organ systems, tissues and portions of the human anatomy, that Applicant proposes at page 190 of the specification, as well as among cancers of 32 other organs and 9 autoimmune diseases at page 208 of the specification, constitutes a "specific" utility. It is the specificity of the disclosure of an alleged utility, rather than the substantiality or the credibility or an alleged utility that is at issue. A claimed invention must posses a specific, substantial, and credible *in vitro* or *in vivo* utility, but the paragraphs to which Applicant points at pages 190 and 208 of the specification are not considered to identify any specific utility for the invention known to the inventors at the time the application was filed where the diffuse assertions at these pages indicate the contrary...The litanies of dozens of disease states with which expression of a claimed polynucleotide is alleged are not evidence that the inventors at the time the application was filed contemplated or recognized a particular, specific, utility for a claimed product."

Applicants disagree with the Examiner's grounds for rejecting Claims 53 to 66 and 76 under 35 U.S.C. § 101 and point out that, while the patent laws as well as current U.S.P.T.O guidance and jurisprudence require that a specification disclose a specific, substantial, and credible or well-established utility, there is no requirement that a specification disclose a utility in any specific manner – rather, the mere disclosure of one specific, substantial, and credible utility or well-established utility is sufficient.

According to the Revised Utility Guidelines Training Materials, a specific utility is defined as "A practical utility which defines a 'real world' context of use" and states that an example of a specific utility is "[a]n assay which measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition – identifies potential candidates for preventative measures or further monitoring". As Applicants argued in the October 18, 2004 Reply to the Examiner's May 17, 2004 Office Action, methods of diagnosing diseases and disorders using nucleic acid- and protein-based technology is standard practice in the art of biotechnology, and that testicular cancer is a real disorder afflicting a significant number of patients each year who are in need of efficacious therapies and diagnostic methods to identify and treat the same. Applicants assert that such a method constitutes a "real world" context of use. In addition, the asserted testicular cancer diagnosis utility of the claimed LSI-01 composition is precisely the type of

"specific utility" provided in exemplary form as guidance by the Revised Utility Guidelines Training Materials since such a diagnostic, by its very nature, "measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition..." and "identifies potential candidates for preventative measures or further monitoring". In this instance, the LSI-01 composition would be the measured material, and testicular cancer would be the disease condition. Clearly, Applicants have met the "specific" utility burden based upon the teachings of Applicants instant specification.

Applicants also point out that the asserted testicular cancer diagnostic utility for LSI-01 also satisfies the "substantial" and "credible" utility requirement as discussed in Applicants October 18, 2004 Reply to the Examiner's May 17, 2004 Office Action. The latter assertion was found to be persuasive by the Examiner since the Examiner states that "[i]t is the specificity of the disclosure of an alleged utility, rather than the substantiality or the credibility of an alleged utility that is at issue", and further states that "...the utilities at pages 190 and 208 of the specification are substantial".

Applicants also point out that the M.P.E.P. clearly that's that "[a] 'specific-utility' is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention." (see M.P.E.P. 2107.01). As Applicants stated in the October 18th, 2004 Reply, the asserted testicular cancer diagnostic utility is "specific" since it is specific to testicular cancer, and not just any disorder. Moreover, Applicants pointed out that this utility is also specific to the claimed LSI-01 polynucleotides and polypeptides, and are not generic to broad class of the serpin family of proteins. Applicants assert that the asserted utility satisfies the "specific" utility requirements as defined by both the M.P.E.P., the guidance provided by the Revised Utility Guidelines Training Materials, as well as in accordance with the patent laws.

Since Applicants specification discloses a specific, substantial, and credible utility for the LSI-01 composition, Applicants assert that the utility requirement has been met and respectfully request that the Examiner withdraw the rejection of Claims under 35 U.S.C. § 101.

The Examiner further alleges that "Applicant neither knew of nor appreciated a specific utility for a claimed polynucleotide at the time the application was filed that would permit an immediate use by the public of a disclosed polynucleotide or any use by the public of an expression vector or host cell comprising a disclosed polynucleotide."

Applicants disagree and point out that the disclosure by Applicants specification that the LSI-01 composition is useful for the diagnosis of testicular cancer is *prima facie* evidence that Applicants both knew and appreciated this specific utility at the time the application was filed. Applicants

specification also explicitly teaches how one skilled in the art can make and use the claimed LSI-01 composition (see Examples 1, 2, 3, and 9), in addition to teaching how one skilled in the art can measure the level of expression of the LSI-01 polypeptide (see Example 4, and 10), in addition to how the skilled artisan can utilize the same in diagnosing a disease condition (see pages 167 to 168). The latter teachings, in conjunction with the specific, substantial, and credible testicular cancer diagnostic utility of the LSI-01 composition asserted by Applicants specification, would clearly be sufficient for a skilled artisan to make and use the LSI-01 composition for this particular utility.

Specifically, the instant specification teaches that "...the invention also provides a diagnostic method useful during diagnosis of a disorder, involving measuring the expression level of polynucleotides of the present invention in cells or body fluid from an organism and comparing the measured gene expression level with a standard level of polynucleotide expression level, whereby an increase or decrease in the gene expression level compared to the standard is indicative of a disorder." (see page 167) in addition to teaching that "[b]y 'measuring the expression level of a polynucleotide of the present invention' is intended qualitatively or quantitatively measuring or estimating the level of the polypeptide of the present invention or the level of the mRNA encoding the polypeptide in a first biological sample either directly (e.g., by determining or estimating absolute protein level or mRNA level) or relatively (e.g., by comparing to the polypeptide level or mRNA level in a second biological sample). Preferably, the polypeptide level or mRNA level in the first biological sample is measured or estimated and compared to a standard polypeptide level or mRNA level, the standard being taken from a second biological sample obtained from an individual not having the disorder or being determined by averaging levels from a population of organisms not having a disorder. As will be appreciated in the art, once a standard polypeptide level or mRNA level is known, it can be used repeatedly as a standard for comparison." (see page 167).

Clearly, the skilled artisan, based upon the teachings of Applicants specification would have sufficient knowledge permitting "an immediate use by the public of a disclosed polynucleotide or any use by the public of an expression vector or host cell comprising a disclosed polynucleotide".

Applicants also disagree with the Examiner's statement that "[t]he litanies of dozens of disease states with which expression of a claimed polynucleotide is alleged are not evidence that the inventors at the time the application was filed contemplated or recognized a particular, specific, utility for a claimed product". As Applicants pointed out to the Examiner in Applicants October 18, 2004 Reply to the Examiner's May 17, 2004 Office Action, polynucleotides and polypeptides have a significant number of utilities that may be above and beyond the asserted utilities. For example, a

polynucleotide may be useful for diagnosing a disease or disorder in one context, while a polypeptide encoded by the same polynucleotide may be useful for treating the disorder in a different context. In addition, a polypeptide may affect a biological pathway that is so basal to cellular function that modulation of the polypeptide would be expected to be useful in treating a number of disorders (e.g., a polypeptide may affect cAMP levels and thus affect all signal transduction pathways utilizing cAMP as a second messenger). Significantly, Applicants are only required to provide evidence demonstrating the claimed invention has a single specific, substantial, and credible utility. The fact that Applicants specification teaches multiple utilities for the claimed LSI-01 composition does not negate whether one or more of the asserted utilities are specific, substantial, or credible, but rather are reflective of the fact that the LSI-01 composition has more than one utility that was conceived by the inventors.

Applicants remind the Examiner that the patent laws only require Applicants to establish that the invention has one specific, substantial, and credible utility in order to satisfy the utility requirement, and makes no restrictions on the number of utilities an Applicant can assert. Specifically, the M.P.E.P. explicitly states "It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (e.g., a machine, an article of manufacture or a composition of matter). However, regardless of the category of invention that is claimed (e.g., product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C.101 and 35 U.S.C.112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. See, e.g., *Raytheon v. Roper* ,724 F.2d 951,958,220 USPQ 592,598 (Fed. Cir.1983), *cert.denied* ,469 U.S.835 (1984)("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C.101 is clearly shown."); *In re Gottlieb* ,328 F.2d 1016,1019, 140 USPQ 665,668 (CCPA 1964)("Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful."); *In re Malachowski*, 530 F.2d 1402,189 USPQ 432 (CCPA 1976); *Hoffman v.Klaus*, 9 USPQ2d 1657 (Bd.Pat.App.&Inter. 1988). Thus, if applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established."

The Revised Utility Guidelines Training Materials are completely consistent with the case law on this point stating the "[i]f there are multiple asserted utilities for a claimed invention, all of them must be either not specific or not credible before a 101/112 utility rejection is made...Stated another way, if one asserted utility is specific and credible, no 101 rejection should be made".

Since Applicants specification clearly has asserted at least one specific, substantial, and credible utility for the claimed invention, Applicants assert that the utility requirement for the claimed invention has been met.

Regarding the Examiner's comment about the "diffuse assertions" of utility in Applicants specification, Applicants pointed out that there is no requirement that Applicants preferred or best utility be disclosed in a specific location or even exemplified as representing Applicants preferred or best utility. According to the MPEP (608.01(h)), "There is no statutory requirement for the disclosure of a specific example. A patent specification is not intended nor required to be a production specification. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1536, 3 USPQ2d 1737, 1745 (Fed. Cir. 1987); *In re Gay*, 309 F.2d 768, 135 USPQ 311 (CCPA 1962). Moreover, the absence of a specific working example is not necessarily evidence that the best mode has not been disclosed...". As Applicants discussed *supra*, the utility of the LSI-01 polynucleotides and polypeptides were clearly disclosed in the instant specification as originally filed. The specificity with which Applicants set forth the "at least one credible utility" is not material to meeting the utility requirement under 35 U.S.C. 101. Rather, the question before the Examiner is whether, based upon the totality of the record disclosed in Applicants specification, including any additional evidence brought forth for review by the Examiner, Applicants have established that the utility requirement has been met in accordance with the preponderance of the evidence standard, as discussed *infra*.

In addition, Applicants October 18, 2004 Reply to the Examiner's May 17, 2004 Office Action was also accompanied by a declaration under 37 CFR § 1.132, referred to as the "Feder Declaration", which demonstrated that LSI-01 transcripts were differentially expressed in testicular cancer tissue relative to normal testis tissue. Specifically, the Feder Declaration stated that "This experiment demonstrates, unequivocally, that, LSI-01, a polynucleotide of the subject U.S. patent application, is differentially expressed in testicular cancers relative to normal testicular tissue..." (see page 1, section 3 of the Feder Declaration). The Feder Declaration also stated that "LSI-01 transcripts were expressed in testicular tumors at a level that was nearly 10 times greater than the observed expression in normal testicular tissue. This data clearly confirms the utility of using LSI-01 expression as a diagnostic marker for testicular cancers." (see page 3, section 4 of the Feder Declaration). This data confirms the utility of using LSI-01 polynucleotides as a diagnostic for testicular cancers.

The Examiner indicated in the present action that the Feder Declaration was not received with Applicants October 18, 2004 Reply. Applicants attribute this error solely to the USPTO as the

Feder Declaration was mailed via Express Mail label concurrently with Applicants October 18, 2004 Reply; is specifically noted as being submitted concurrently with Applicants Reply "Submitted concurrently herewith is...a Declaration pursuant to 37 C.F.R. §1.132, including its accompanying Exhibits A, and B" (see first paragraph of Applicants October 18, 2004 Reply); and is relied upon by Applicants in the arguments presented throughout the October 18, 2004 Reply. It is unclear to Applicants why such a Declaration was separated from Applicants Reply, let alone why it was lost subsequent to the same. Clearly, the Feder Declaration should have been received by the USPTO. Private PAIR confirms the Examiner's allegation that the Feder Declaration was not acknowledged by the USPTO. Although Applicants internal files clearly indicate that the Feder Declaration was submitted concurrently with Applicants October 18, 2004 Reply, Applicants have provided a courtesy copy of the Feder Declaration for the Examiner's consideration.

Applicants assert that the utility of LSI-01 polynucleotides as a diagnostic for testicular cancers represents a specific, substantial, and credible utility and that the Examiner's rejection has been overcome in consideration of the teachings of Applicants disclosure as originally filed, the arguments presented above, in addition to the corroborative evidence provided by the Feder Declaration.

Although the Examiner apparently did not have the benefit of reviewing the Feder Declaration prior in drafting the instant action, the Examiner nevertheless appears to reject that which he has not seen, stating that "[h]ad the Declaration been present for consideration, it is not agreed that it could be dispositive of the issue of a disclosure of a specific utility known to the inventors at the time the application was filed because Applicant's arguments in the Response indicate that experimentation was conducted after the application had been filed, and because the diffuse assertions of utility to which Applicant points, among other equally diffuse assertions elsewhere in the specification, are strong evidence that the inventors neither recognized nor appreciated any utility specific to a claimed polynucleotide at the time the application was filed."

Applicants disagree with the basis of the Examiner's assertions for the reasons exemplified *supra*. Specifically, Applicants specific disclosure of the testicular cancer diagnostic utility of the LSI-01 composition in Applicants specification, as discussed *supra*, represents *prima facie* evidence that the inventors recognized and fully appreciated the specific utility at the time the application was filed. Moreover, and as discussed *supra*, the fact that Applicants specification discloses multiple utilities conceived by the inventors for the LSI-01 composition does not negate a finding that LSI-01

has utility as the patent laws only require Applicants instant specification to disclose one specific, substantial, and credible utility.

The Examiner's allegation that the time at which an experiment is performed to confirm an asserted utility is relevant in the determination of whether a specific utility has been established for an invention is inconsistent with the patent laws, the USPTO's own guidance, as well as judicial precedence.

First, Applicants point out that, contrary to the Examiner's statements, that neither the Feder Declaration nor Applicants October 18, 2004 Reply, provides any rational basis for either suggesting or concluding that "...experimentation was conducted after the application had been filed". Applicants request that the Examiner appropriately correct the record by acknowledging the same. Nevertheless, the Revised Utility Guidelines Training Materials specifically provide that "New evidence" may be provided by Applicants in the form of either a "Declaration under 37 CFR 1.132" or via a "Printed publication" in supporting an asserted utility. It is important to note that such evidence is distinguishable from "new matter" since such evidence is brought forth to support a utility already asserted within the specification and is not considered part of the specification.

Secondly, Applicants bring to the attention of the Examiner a recent case before the United States Court of Appeals for the Federal Circuit, Knoll Pharmaceutical Company, Inc. v. Teva Pharmaceuticals USA, Inc. (No. 03-1300 (Fed. Cir. May 19, 2004)). The issue before the court was whether a patent holder can properly bring forth evidence demonstrating unexpected benefits or results for a composition after a patent has been granted when the validity of the composition is alleged to be obvious. Applicants acknowledge the issue before the Examiner is not the same as the issue decided by the Federal Circuit, however, Applicants believe the rational utilized by the court in arriving at their decision is analogous to the issue presented here. The court states that:

> "Evidence developed after the patent grant is not excluded from consideration, for understanding of the full range of an invention is not always achieved at the time of filing the patent application. It is not improper to obtain additional support consistent with the patented invention...There is no requirement that an invention's properties and advantages [be] fully known before the patent application was filed, or that the patent application contains all of the work done in studying the invention, in order for that work to be introduced into evidence...Nor is it improper to conduct additional experiments and provide later-obtained data in support of patent validity."

Applicants believe the decision in Knoll v. Teva is applicable here in supporting the argument that the time an experiment is performed to support validity of an invention, whether it be

to contest a challenge to validity during litigation or in establishing the credibility of an invention for purposes of satisfying the utility requirement, is inconsequential and not a proper basis for failing to fully consider evidence brought forth by Applicants via Declaration.

In consideration of the forgoing arguments, Applicants believe the Examiner's statement that "[r]etrospective demonstration of one among many prospective, potential, utilities cannot rise to the level of a credible assertion of a specific *in vivo* or *in vivo* utility recognized and appreciated by the inventors at the time the application was filed" is in error on the basis that it is not in conformance with USPTO guidelines, the patent laws, nor jurisprudence, and request appropriate correction in the record.

Nonetheless, Applicants also point out that this portion of the Examiner's Action is largely moot since the only issue properly before the Examiner is whether Applicants specification has disclosed a "specific" asserted-utility, since the Examiner has already acknowledged that Applicants asserted utility is substantial and credible as discussed *supra*.

Since Applicants have clearly asserted at least one specific, substantial, and credible utility for the claimed invention, and have provided proof, in the form of a Declaration under 37 C.F.R. 1.132 (the "Feder Declaration"), confirming the credibility of one of the asserted utilities. Applicants assert that the utility requirement for the claimed invention has been met.

In addition, Applicants would like to remind the Examiner that, in accordance with the guidance provided in M.P.E.P. 2107.02, the Examiner is required to operate under the presumption that "a statement of utility made by an applicant is true" (*In re Langer*, 503 F.2d at 1391, 183 USPQ at 297) and that the Examiner "must accept an opinion from a qualified expert that is based upon relevant facts" and that it is "improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered" (see M.P.E.P., 8th Ed., 2107). Where a question remains relative to the truth of a statement of utility, the Examiner is required to evaluate "the logic of the statements made, taking into consideration any evidence cited by the applicant." The standard to be utilized by the Examiner in evaluating the patentability of the invention "is determined on the totality of the record, by a preponderance of evidence" (In re Corkill, 771 F.2D 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985)). "Totality of the evidence exists when it suggests that it is more likely than not that the assertion in question is true. Herman v. Huddleson, 459 U.S. 375, 390 (1983))...To do this, Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art...This means that if applicant has presented facts that support the reasoning used in asserting a

utility, Office personnel must present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicants assertion of utility (In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995))".

Applicants assert that the evidence presented in the Feder Declaration clearly confirms Applicants asserted testicular cancer diagnostic utility of LSI-01, that the evidence is credible to one skilled in the art, and that it meets the preponderance of the evidence standard.

Applicants also assert that the Examiner's rejection of the Feder Declaration constitutes an action that disregards an opinion (i.e., statements brought forth within the "Feder Declaration") provided by a qualified expert. Such an action is clearly contrary to the guidance provided in the M.P.E.P as noted *supra*.

Applicants also point out that according to the M.P.E.P., "Rejections under 35 U.S.C. § 101 have been rarely sustained by federal courts...in these rare cases, the 35 U.S.C. § 101 rejection was sustained either because the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a low of nature, or was wholly inconsistent with contemporary knowledge in the art". As discussed *supra*, and in Applicants October 18th, 2004, Reply, Applicants specification clearly disclosed a specific utility for the LSI-01 polynucleotides, in this case the testicular cancer diagnostic utility. Moreover, as stated in the Feder Declaration, "Comparison of the expression profiles obtained from normal and diseased tissues is a common method of associating the expression and/or misexpression of a protein to a specific disease and/or disorder." Clearly, the experimental data showing LSI-01 is useful for diagnosing testicular cancer, as corroborated in the Feder Declaration, is fully consistent with contemporary knowledge in the art regarding such methods and their interpretation.

Applicants believe the Examiner's maintenance of the rejection of Claims 53 to 66 and 76 under 35 U.S.C. § 101 is in error for the reasons outlined *supra* and request that the Examiner withdraw the rejection accordingly.

II. Rejections under 35 U.S.C. § 112, first paragraph

a. The Examiner has rejected Claims 53 to 66, and 76 under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner has rejected Claims 53 to 66, and 76 alleging that since "the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention

Applicants disagree and believe the Examiner's arguments have been overcome in consideration of the arguments presented *supra* and elsewhere herein, in addition to the Feder Declaration submitted under 37 C.F.R. § 1.132 with Applicants October 18th, 2004, Response. Applicants request that the Examiner respectfully withdraw the rejection of Claims 53 to 66, and 76 under 35 U.S.C. § 112, first paragraph.

The Examiner further alleges that "Applicant...does not establish that enablement of a specific use of a claimed product is disclosed in the application as of its effective filing date of November 14, 2000."

Applicants disagree and point out that the teachings of Applicants instant specification, in addition to U.S. Provisional Application Serial No. 60/248,434, filed November 14, 2000, representing the earliest application from which the instant specification relies upon for benefit of priority, fully enables the LSI-01 composition in addition to the testicular cancer diagnostic utility asserted by Applicants. Specifically, the instant specification explicitly teaches how one skilled in the art can make and use the claimed LSI-01 composition (see Examples 1, 2, 3, and 9), in addition to teaching how one skilled in the art can measure the level of expression of the LSI-01 polypeptide (see Example 4, and 10), in addition to how the skilled artisan can utilize the same in diagnosing a disease condition (see pages 167 to 168). Additionally, U.S. Serial No. 60/248,434 also explicitly teaches how one skilled in the art can make and use the claimed LSI-01 composition (see Examples 1, 2, 3, and 9), in addition to teaching how one skilled in the art can measure the level of expression of the LSI-01 polypeptide (see Example 4, and 10), in addition to how the skilled artisan can utilize the same in diagnosing a disease condition (see pages 131 to 132).

Applicants believe the Examiner's arguments have been overcome in consideration of the arguments presented *supra* and elsewhere herein, in addition to the Feder Declaration submitted under 37 C.F.R. § 1.132 with Applicants October 18th, 2004, Response. Applicants request that the Examiner respectfully withdraw the rejection of Claims 53 to 66, and 76 under 35 U.S.C. § 112, first paragraph.

Applicants believe that all of the Examiner's rejections and objections have been overcome and that all of the pending claims before the Examiner are in condition for allowance. An early Office Action to that effect is, therefore, earnestly solicited.

If any fee is due in connection herewith not already accounted for, please charge such fee to Deposit Account No. 19-3880 of the undersigned. Furthermore, if any extension of time not already

accounted for is required, such extension is hereby petitioned for, and it is requested that any fee due for said extension be charged to the above-stated Deposit Account.

Respectfully submitted,

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